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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,949	01/07/2002	Jeffrey H. Burbank	265/064	5362
22249	7590	11/19/2003	EXAMINER	
LYON & LYON LLP 633 WEST FIFTH STREET SUITE 4700 LOS ANGELES, CA 90071			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/041,949	BURBANK ET AL.
	Examiner	Art Unit
	Patricia M Bianco	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 07 January 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-155 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-155 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.    |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input checked="" type="checkbox"/> Other: <i>Restriction Requirement</i> . |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-55 & 98-134, drawn to a fluid circuit assembly or fluid management system, classified in class 604, subclass 4.01.
- II. Claims 56-85, drawn to a fluid circuit having two pathways, fluid chambers, an element to hold the chambers, and a flow bypass region, classified in class 210, subclass 254.
- III. Claims 96-97, drawn to a fluid processing system having a processing machine, a disposable fluid processing circuit, and a cartridge holding first and second fluid pathways, classified in class 210, subclass 252.
- IV. Claim 135, drawn to a method for monitoring pressure in a blood processing system, classified in class 210, subclass 741.
- V. Claim 136, drawn to a method for detecting a blood leak in a blood processing system, classified in class 210, subclass 745.

The inventions are distinct, each from the other because of the following reasons:

Inventions I & II / I & III / I & IV / I & V / II & III / II & IV / II & V / III & IV / III & V and IV & V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). With respect to invention I, the invention is different from inventions II, III, IV & V since they are not

usable together and have different effects. With respect to invention II, the invention is different from inventions III, IV & V since they are not usable together and have different effects. With respect to invention III, the invention is different from inventions IV & V since they are not usable together and have different effects. With respect to inventions IV & V, they have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

If applicant chooses to elect the invention of **Group I**, a further election of species is required.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: First and second fluid pathways and an element to hold the pathways in overlapping alignment;

Species B: First and second sheets defining first and second compartments in overlapping alignment;

Species C: First and second fluid pathways defining first and second compartments in overlapping alignment;

Species D: First and second fluid pathways defining first and second compartments in overlapping alignment and defining a gap;

Species E: First and second fluid pathways defining first and second compartments and having a plurality of channels defined and in communication with the panels, wherein the panels overlay one another;

Species F: First and second fluid pathways defining first and second compartments and having a plurality of channels defined and in communication with the panels, wherein the panels overlay one another, and a clamp against the first and third channels.

If applicant chooses to elect the invention of **Group II**, a further election of species is required.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species G: A method using a fluid circuit for conveying an incoming fluid and a replacement fluid in response to one another (claims 77-81);

Species H: A method of processing blood using a fluid circuit including separating a material from the blood and conveying replacement fluid to the patient in response to the separated material (claims 82-85).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is considered to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

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November 14<sup>th</sup>, 2003